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To: UC-COMP-MATTERS@LISTSERV.UC.EDU
Subject: [UC-COMP-MATTERS] Compliance Matters: Summer 2015
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OFFICE OF RESEARCH INTEGRITY
UNIVERSITY OF Cincinnati
Compliance News Quarterly MATTERS

Summer 2015

Did you know that shipping carries personal liability? International shipments are considered a physical export regardless of what you are shipping (even employment paperwork). You should consult with the export control officer before you ship; these items or documents may require a federal export license. The regulations are difficult to interpret and non-compliance may result in confiscation of items, severe fines and other penalties. The Export Control Office will work with you to protect you and your shipment. Get more information about export controls and international shipping.
Regardless of the destination (inside or outside of the U.S.), if you are shipping biologics you must have current IATA training (available online).

NIH Announcement
Dr. Carrie Wolinetz, associate director of science policy at the National Institutes of Health (NIH) has launched a blog "Under the Poliscope: Bringing Science Policy Into Focus," which highlights the NIH Office of Science Policy, science policy matters and emerging issues of interest to the life sciences community and public at large.
As always, if you have a suggestion that will help us to help you, please contact us at research.compliance@uc.edu.

Jane Strasser, PhD
Director, UC Office of Research Integrity
Research Compliance Officer
Research Integrity Officer

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ANIMAL CARE AND USE UPDATE

Need to Collaborate With Other Researchers Using Animals?
As researchers continue to struggle with cutbacks to federal, state and local funding, being able to increase opportunities for collaborative research and collection of crucial pilot data is a must in order to remain competitive and successful. The current protocol transfer process allows for the timely transfer of animals between protocols and for flexibility regarding which of the collaborators will cover the cost of per diems or other service fees.

To transfer animals, complete the Protocol Transfer Form (PDF) which contains three parts:

- The first part identifies the protocol from which the animals are coming and obtains

authorization to move the animals

- The second part identifies the protocol that will be receiving the animals and obtains authorization to move the animals
- The third part is to identify who will cover the cost of per diems or other service fees

For assistance with this process, please contact Christy Matu (matucl@ucmail.uc.edu, 513-558-6072), Jermaine Houston (houstojo@ucmail.uc.edu, 513-558-5177), or Steve Ribar (ribarsl@ucmail.uc.edu, 513-558-5160).

Deactivation of Cage Cards

Laboratory Animal Medical Services (LAMS) uses cage cards with bar codes to identify all cages housing animals at UC as well as to bill daily per diems to researcher's accounts. When a researcher completes a study and has cages that no longer contain animals, it is imperative that the cage cards be deactivated so no additional charges associated with those cages are billed. There are red, deactivation boxes at the entrances of each vivarium and in the necropsy rooms. Simply write the date (month/day/year) on the cage card and drop the card in the deactivation box. You need to repeat this process for each card needing to be deactivated. Cage cards with no deactivation date or those not placed in the deactivation box will continue to accrue per diem charges until the cage card has missed two consecutive weekly scans.

Procedures

Familiarity and proficiency with any procedure is key in research. Some procedures—euthanasia, for example—require training (including documentation of training) and persons performing this procedure must be knowledgeable and proficient in techniques listed on the approved Institutional Animal Care and Use Committee protocol. For more detailed information and training in acceptable methods, please contact the Laboratory Animal Medical Services (LAMS) Attending Veterinarian, Joanne Tetens-Woodring, DVM, at tetensje@ucmail.uc.edu or 513-558-5518.

Appropriate Attire in the Animal Facilities

With the warm weather and high humidity upon us, more people are coming to work wearing shorts, skirts, and/or sandals. It is important to remember that just as in being in a laboratory, there is a specific dress code for entering and working in any LAMS vivarium. Specifically, shorts, skirts and open-toe shoes are not permitted due to personnel safety issues. It is best practice to have available a pair of scrubs (or equivalent) and closed-toe shoes to change into before coming to the vivarium. If you have any specific questions regarding entering and working in the vivarium, please send an e-mail to lams@uc.edu.

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BIOSAFETY INFORMATION

Animal Containment: Human Xenograft

To minimize the risk of exposure in experiments involving transplantation of human cells into animals, preparation of injection (e.g., syringe loading) and the administration of cells must occur within an ABSL2 area utilizing containment equipment, such as a biosafety cabinet. In cases where use of containment equipment is not feasible, the use of PPE for mucosal protection is required. Following injection/transplant, the site of administration must be properly disinfected and the animal returned to the cage which can be transferred to a regular housing area.

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EXPORT CONTROLS UPDATE

International Shipping

Are you shipping items internationally? Are you collaborating internationally? Are you traveling internationally to visit another institution or company? U.S. export control laws, regulations, and executive orders apply to these efforts. You must "KNOW YOUR CUSTOMER" by conducting restricted party screenings prior to commencement of the activity.

Please contact the Export Controls Office (exportco@uc.edu) for more information and to obtain access to the online screening tool, Visual Compliance.

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HUMAN RESEARCH PROTECTION PROGRAM NEWS

IRB Billing

The infrastructure that supports the Institutional Review Board (IRB) is funded by the indirect (F&A) return on expenditures. That cost is not captured when the funding is run outside of UC (e.g., if the contract runs through UC Health or CERV). If studies are receiving external funding and are using UC's IRB, the following fees apply:

- Initial Review — $2,000
- Fast-track review of Initial IRB protocol submission — $5,000
- Exempt review of Initial IRB protocol submission — $500
- Continuing Review Fee — $1,000
- Changes and/or Modifications (Amendments) — $250

There is no charge for administrative modifications (i.e., study personnel changes or site additions) or submission of reportable events (i.e., unanticipated problems, adverse event/serious adverse event, protocol deviation).

Please visit the IRB fee page for further information.

Research Conducted at the VA

The Veterans Affairs (VA) Office of Research Oversight has revised Handbook 1058.01 (issued June 15, 2015). Researchers are required to provide **immediate verbal notification** to the IRB of any local research **death** that is **both** unanticipated **and** related to the research. Researchers are required to submit written notification to the IRB within five business days of incidents that are both unanticipated and related to the research.

Reportable Events in ePas

When the IRB determines that corrective and/or preventative action is required to address a reportable event, follow-up reports summarizing actions taken and/or planned need to be submitted as a separate reportable event in ePas. When you are completing the smart form for an update, use the same name on question No. 1 given on the initial reportable event. Select the same radial button describing the type of event (question No. 2) utilized in the initial submission. Ensure that you mark "Yes" for question No. 3, when asked if the reportable event submission is a follow-up to a previous submission for the study. Please contact your designated HPA with any questions or concerns.

Tips for Researchers:

- Data Safety Monitoring Board reports that do not include findings for IRB review may be submitted during continuing review.
- When collaborating with researchers at other institutions or conducting research in other countries, please contact the Human Research Protection Program office to discuss the process prevent delays.
- When excluding a group of people from your study population, explain why it is necessary for the study.

- Recruitment materials intended for use via Facebook, Twitter, email or other social media for study recruitment must be submitted to the IRB for review and approval. These recruitment methods do not provide adequate protections for personally identifiable information. Researchers should provide prospective subjects a mechanism for contacting the study team such as phone, email or other methods that do not involve social media messaging.

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RADIATION SAFETY

Pregnancy and Radiation Protection

Studies have indicated an increased sensitivity of the embryo/fetus as compared to an adult; therefore, regulatory agencies have adopted special dose limits for a declared pregnant worker. The special dose limits are designed for protection of the embryo/fetus.

The UC Radiation Safety Officer is always available to discuss workplace exposure, the risks associated with exposure to ionizing forms of radiation, dosimetry, procedures to minimize radiation exposure and dose received during the pregnancy.

Please visit the U.S. Nuclear Regulatory Commission (NRC), Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure" (PDF) for frequently asked questions about pregnancy and radiation protection.

Additional information can be found on both the NRC and the Centers for Disease Control and Prevention's website, or you may call the UC Radiation Safety Office at 513-558-4110 to schedule a meeting with the Radiation Safety Officer.

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TRAINING OPPORTUNITIES

Human Subjects Protection Conference

The 17th Annual Human Subjects Protection Conference will take place on Thursday, Oct. 1, 2015, in Covington, Kentucky, at the Northern Kentucky Convention Center.

This year's conference offers a new second day of programming by Public Responsibility in Medicine and Research (PRIM&R) on Friday, Oct. 2, 2015.

To register, visit www.cincinnatichildrens.org/cme and click the "Continuing Education Portal" link on the right. Use the discount code: "IRB" when registering to receive a $100 "early bird discount." This code will work for both conferences. For more information, view the full conference brochure.

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